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April 2, 2003

Subject: CCMA Statement on the U.S. Food and Drug Administration's proposed Regulations on Prior Notification of Imported Food, Docket Numbers 02N-0278 and 02N-0276, March 21, 2003

These comments are submitted by the Canadian Courier & Messenger Association (CCMA), in response to the *Federal Register* notice in which the Food and Drug Administration (FDA) proposes regulations requiring prior notification and registration of food facilities for imported food as authorized under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

To give you some background on our organization, the CCMA is the trade association representing time sensitive delivery service company operations of all types and sizes across Canada by providing professional, informed and proactive representation and information on common issues. Our members include; large firms with global delivery networks, such as DHL, Emery, FedEx, Purolator, TNT and United Parcel Service, overnight transborder integration firms, mid size local and regional delivery firms with strong area distribution networks and smaller local firms such as same day and messenger companies maintaining an extensive stake in the time sensitive shipping business.

The Canadian Courier market itself is estimated to be worth approximately 5 billion dollars annually and translates to the movement of almost 2 million packages per day. This vital sector of the Canadian economy is made up of approximately 2,400 courier companies employing nearly 55,000 people utilizing 14,000 delivery vehicles, hundreds of aircraft and over 400 local sortation centers. Worldwide, CCMA members have operations in over 200 countries; move more than 20 million packages each day; employ more than 800,000 people; operate 1,200 aircraft; and earn revenues in excess of $50 billion annually.

The express transportation industry specializes in time-definite, cost effective, reliable transportation services for documents, packages and freight and has solidified itself as an important contributor to the economic success of world economies. Express delivery has vital importance to businesses utilizing time-sensitive, "just-in-time" manufacturing techniques and supply-chain logistics in order to remain internationally competitive.

We rely heavily on the highest level of technology of any mode to control the movement of enormous volumes of time sensitive goods with tight delivery "cycle times," some using advanced targeting methods developed internationally, proven to intercept contraband and threats to security. For many years our industry has worked in close partnership with government agencies globally, whose prime objective is to support the delicate balance between trade facilitation and security.

International trade is the lifeblood of the global community. In Canada, 47% of our GNP is produced through international trade. It is our opinion that we must safeguard, develop and support any measures that facilitate sustainable competitiveness in international trade and be cautious not to stifle such initiatives.

The intent of the proposed legislation cannot be disputed, the CCMA supports the US FDA's goal towards defending the food supply which is a fundamental expectation of U.S. and Canadian citizens on the food imported into their respective countries, but the methods proposed may turn the world's two largest trading partner's border into an administrative dilemma.

Our initial assessment is that these regulations will impose significant to potentially impossible administrative obstacles. We are concerned that we have in essence a very short time frame to comment and collaborate on such a wide ranging and potentially significantly trade disruptive and administratively difficult set of regulations. We wish to seek a common and practical approach through working with the FDA that addresses the needs of the Bioterrorism act, yet does not impede or add cost to what has been a mutually beneficial and largely problem free trade between our two countries.

The air express industry plays a fundamental role in the supply of goods within very demanding timetables; packages are often dispatched within hours as our industry serves as a support system to keep vital commercial entities functioning. The trans-border element of our industry is comprised largely of integrated carriers who provide an entire spectrum of services to support trade. We are often the carrier, customs broker and the agent for a majority of our clientele in import matters, including FDA clearance. For this reason, the proposed regulations impact the single most significant time sensitive modes; express operators and truck as much as the importer of the goods. The draft acknowledges the largest threat is from offshore, yet the regulations most severely hit continental trade between the U.S. Canada and Mexico.

The FDA's proposal to establish prior notification of food products by noon of the calendar day prior to arrival would severely disrupt the international express services our members provide and impact trade entities that depend on express services to survive and remain viable in the global economy.

Imposing stricter reporting requirements than today would cause catastrophic damage to our industry and its customers**.** FDA's goal with these regulations is to facilitate tracking of the U.S. importer or consignee and monitor corresponding imports. Our industry already meets this goal without any new prior notification requirements.

Express operators place tight controls throughout time sensitive transportation practices at operations subject to high-security, documentary, physical and staff precautions ensuring the security of packages guarding against unauthorized delivery to the importer or consignee prior to proper clearance by relevant government agencies.

Our industry has collaborated extensively with U.S. Customs and the Transportation Security Administration to develop procedures that achieve security objectives. In addition, we provide Customs the most detailed and automated shipment data of any mode of transportation. This data is filed in advance of arrival and is available for use by the USFDA. Today we hold food shipments at the original port of entry or the final port of destination pending the FDA's approval and authorization to deliver the shipment to the importer or consignee. The time sensitive nature of our business warrants that the required information for food products is submitted to the FDA's OASIS system as early as possible prior to arrival, hence advance notice is provided in today's environment.

The information required in the proposal would do little towards improving security and would not be a critical determining factor in targeting or determination of what shipments should be examined or tracked

for follow up. The information currently presented in OASIS provides an adequate measure of security for imports to the U.S. and has been performing well for many years. For these reasons, we strongly urge the FDA to utilize OASIS for any prior notice declaration.

Since the OASIS system already is in existence, enhancements to this system or the procedures involved would be preferable to traders as the connectivity and current procedures already exist. A new stand alone web-based system would be costly to the trade and government to implement and execute. A flexible approach such as augmenting the existing infrastructure and providing a web portal to the existing OASIS system would give access to additional suppliers globally and would achieve FDA goals while keeping costs reasonable with current information providers having existing communication links.

Registration
Rather than radically imposing new advance notice timeframes, the two governments (U.S. and Canada) would be more effective by developing mutually agreed upon criteria that their respective exporters must meet, maintain a registry that is mutually accessible to each government, and is electronically linked to each other's Customs systems. Failure to be in this registry would negate the ability to move product into each other's country. This would place the onus for attention and secondary review effectively at the greatest point of potential threat, unknown and higher risk entities. Such a registry may reduce enforcement at the border during the time sensitive phase of the shipments movement provided the exporter and carrier have a low risk profile. It might eliminate or diminish the need of many of the administrative requirements which would be burdensome to non-problematic or non-threatening industry in both countries.

Existing Registration
For the fresh fruit and vegetable sector, there already exists, in both countries, a system of licensing or registration for firms that export to each other. Perhaps this is a suggested place to start, rather than create another system, build upon the one that already exists. e.g. PACA, DRC and the CFIA. We appreciate these registration systems do not fall under USFDA or Canada's Food Inspection Agency (CFIA), but the fact remains that our two governments already have a system of identification for firms that trade into each other's country. This may be an option that warrants examination by the two governments and industry.

It also would mean each country would have to develop mutually agreed upon standards as to the information needed to reassure each other of the minimization of potential threat; and to develop criteria for reviewing registrants. If the regulations are critical to meet U.S. and Canadian food security objectives, this alternative may replace for the majority of commerce, and majority of legitimate traders, administrative obstacles which would find them unable to trade, or in a constant situation of being in violation, and consequently subject to criminal action.

Minimum Notice Analysis
The draft proposes that FDA draw a representative sample of the enormous volume of trucks and other time sensitive transportation modes from Canada as part of their efforts to underpin the minimum notice time frame, we feel this is the correct approach but in addition a thorough understanding of transportation patterns, practices and operations are key to this decision making process as well as consideration of the economic impacts. The majority of food exports are within three hours of the U.S. border. A factual, accurate registration system placing the onus on unknown entities is preferred to any provision of prior notice pre-arrival by the very nature of the time sensitivities inherent to these types of products and the modes that move them.

In addition to the concerns we have regarding the proposed time frames, increased data and the means to communicate same, CCMA would like to highlight the following areas for consideration, review and collaboration prior to finalization of the regulations and procedures:

Prior Notification Exemptions – personal use
The proposed regulations specifically mention some exemptions to the prior notification requirements; namely, food products carried by individuals entering the U.S. as part of the individual's personal baggage that are intended for personal use. We assume this exemption also applies to shipments of food products imported via common carriage that are part of an individual's unaccompanied baggage and are intended for

personal use. Food products entering the country whether imported via a common carrier or as part of accompanied baggage entering with the individual should be treated the same. The proposed regulations should clarify this issue and contain specific language to this effect. Further, small shipments of nominal value for personal, non-commercial use should be similarly exempted from the requirement for prior notification. The express industry handles many of these shipments now, which include purchases from a growing number of Internet-based sellers. Small shipments of this type for personal use do not qualify as a risk to the domestic food supply, and should therefore be considered outside the scope of the requirement for prior notification.

De Minimis rule establishment

The proposed regulations also fail to establish a value threshold for shipments subject to the prior notice mandate. Submitting prior notices for shipments of *de minimis* value (i.e., less than $200) would not benefit the FDA or the trade. A de *minimis* rule consistent with that of U.S. Customs should be established, and such shipments should be exempted from the prior notification requirement.

In Transit Shipment Treatment

Subpart 1.276 of the proposed regulations identifies the imported foods that are subject to the new requirement, and includes shipments that will be immediately exported from the port of entry and transshipments through the United States to other countries. CCMA is concerned that the FDA would require the submission of prior notifications for transit shipments. In the express industry, there are tens of thousands of such shipments, and more importantly, in the vast majority of cases transit shipments do not remain in the country longer than 24 hours. During the brief time the shipments are in the country, they are under the strict control of the express operator. It is highly unlikely that any of these shipments would be inadvertently delivered in the United States. Submitting prior notifications for transit food shipments would present a tremendous burden for our industry, requiring substantial procedural and process changes that would be very costly for the industry and customers to implement. It is unclear how prior notifications for transit shipments would benefit the FDA or reduce the threat to public health, and we urge the FDA to exclude these shipments from the scope of the new regulations.

Delay of Non-food consolidated cargo

CCMA is also troubled by the draft's proposal that, "when mixed consolidated freight contains articles of food that must be held at the port of entry those articles must be dealt with before the rest of the shipment proceeds." This could wreak havoc with shipping schedules in the express industry, and is simply not justified. Non-food commodities, and commodities not regulated by FDA, should not be delayed for FDA processing of regulated articles.

Holding Facilities Expansion

The proposed regulations create a category and definition of a "holding" facility for imported food articles, which would be required to register with FDA. The definition of "holding" as proposed should not include carrier facilities that merely "hold" or stage goods as an incidental occurrence to the transportation from a shipper to a consignee. Such delay may occur for a variety of reasons, for example, while FDA clearance is in process, or while the shipment simply awaits transfer to another carrier. "Holding" or storage is distinctly different from transportation, and is clearly not part of an express carrier's transportation offering. A "holding" facility would clearly be defined as owners, operators, or agents in charge of facilities engaged in manufacturing, processing, packing, storing, or warehousing food for consumption, and would therefore not include a carrier providing transportation services. We recommend that the proposal be revised as follows to clarify these issues:

- Add a new subsection 1.226(h) as follows: "1.226(h): Air, ocean, or surface transportation companies providing transportation and related services for import to the United States." Holding" or "manufacturing/processing" activities as defined in part 1.227 would require registration."

- Add the following sentence to 1.227(5): "The temporary staging in a carrier's facility of a shipment in transit from a shipper to a consignee which is incidental to the transportation is not holding or storage for purposes of this definition."

USFDA Codes
USFDA refers to use of a code which we understand is a potential new code that will certainly create more confusion and administration. We recommend use of the Harmonized System Tariff Codes (HS) that are already provided to U.S customs and understood by many global industry sectors involved in trade. Creation of new coding systems will in the end create increased costs, confusion, meaningless information and errors for the USFDA and the trade.

Notice Party
The party authorized to supply the notice to the FDA should be flexible including the Canadian exporter or authorized agent acting on behalf of the exporter or importer. This will reduce time delays, reflect reality, and will increase accuracy, to do otherwise or make it the responsibility of the U.S. party would result in U.S. buyers turning away from Canadian shippers and products due to increased administration and costs.

Amendment Procedures
The limitations as to what information may be amended must be examined. The process and timelines to change arrival information is unnecessarily strict. If a shipment is arriving more than one hour prior to the time initially notified or more than three hours later than notified initially the update to the original prior notice required by the FDA will be extremely problematic for many exporters.

Universal Database
An additional concern is the draft's statement that "any information that would disclose the identity or location of a specific registered person is not subject to disclosure (to the public)." Unless there is some reference database available to traders, it could be quite difficult to comply with the regulation. If the registration number must be submitted, a universal database must be available for all to review.

Packaging concerns
We understand that any product (e.g. packaging) that touches the food product needs to be registered also. If this is the case, we require further definitions as to how the registration and reporting process would operate for these scenarios. This could include plastic wraps, paper cartons/containers leading to an extremely problematic administrative situation.

Link/unite government agencies
The U.S. receives much information already prepared by Canadian exporters and provided to the US government by U.S. customs brokers. We recommend building on what already is in place and not creating something separate solely for USFDA as U.S. Customs is the front line of enforcement. Closing the loop between various U.S government agencies (e.g. USFDA, USDA, U.S. Commerce and U.S. Customs) would provide tremendous benefits in operational synergies for trade, while at the same time providing a greater margin of control and tracking. By the same measure this is exactly what needs to occur within Canada for imports with CFIA, DFAIT, CCRA and Heath Canada and other government agencies concerned with Canadian import concerns.

FDA 24/7 Infrastructure
As a final comment, the CCMA is concerned about the FDA's ability to support this new mandate from a staffing perspective. Unless FDA can have staff available 24/7 to answer questions and to process the additional declarations submitted in the OASIS system, implementing the regulations would significantly impede the flow of commerce.

We emphasize the importance for engagement of multilateral efforts to develop and assess the commercial implications of the proposed regulations. It is critical that this include USDA, US Commerce, U.S. Customs and key Canadian counterparts. We also suggest Mexico be included, the largest commerce remains between our three countries, we share the borders (and therefore the challenge). It is still not clear how the new regulations will affect movement between Canada and Mexico or offshore to Canada, a significant portion which moves through the USA. We would highly recommend that our government form a specific consultation group with all interested parties to address food sector issues, from an export and import perspective.

The CCMA ardently supports efforts to improve security of the U.S. food chain via the implementation of feasible initiatives that acknowledge trade facilitation requirements. We are pleased that the FDA indicates a willingness to inform and fully consider all comments. We believe the optimum method to achieve this worthy goal is through a stakeholder working group that can fully consider the ramifications of all facets of this matter and develop viable recommendations. We urge that this type of group work toward achieving an industry supportable method of addressing USFDA requirements, aiding in its targeting efforts while balancing the economic realities of avoiding damage to the express industry and the global economy with implementation on a practical prospective basis.

We appreciate the USFDA's consideration of these comments ensuring Canadian concerns are voiced and taken into consideration. I thank you in advance for your attention and consideration of our letter. If you have any questions or wish to schedule a future meeting in this regard I can be reached directly at 905 257 7027 or pcahley@canadiancourier.org

Sincerely,
Phil Cahley

Executive Director